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P R O C E E D I N G S

11:12 AM

MS. O'LONE: Welcome to the General Hospital and Personal Use Devices Panel Meeting. My name is Martha O' Lone, and I am the Executive Secretary for the General Hospital and Personal Use Devices Panel, and I would like to welcome everyone to the Panel meeting today, and if you have not signed in, please do so at the sign-in desk just outside the room. I think I saw most of you had signed in.

Also, at the sign-in desk I did have copies of the agenda and information on obtaining a transcript of today's meeting.

To begin this meeting I have two statements that must be read into the record, and the first is the conflict of interest statement for the General Hospital and Person Use Devices Panel Meeting for today.

The following announcement addresses conflict of interest issues associated with this meeting and is made part of the record to preclude even the appearance of an impropriety. The conflict of interest statutes prohibit special government employees from participating in matters that could affect their or their employers' financial interests .

To determine if any conflict existed the agency reviewed the submitted agenda and all financial interests reported by the Committee participants.

The agency has no conflict to report. In the event the discussions involve any other products or firms not already on the agenda for which an FDA participant has a financial interest the participant should excuse him or herself from such involvement, and the exclusion will be noted for the record.

With respect to all other participants we ask in the interests of fairness that all persons making statements or presentations disclose any current or previous financial involvement with any firm whose products they may wish to comment upon.

Also, for the purpose of today's meeting we have an appointment to temporary voting status for two of the panelists, and it is signed by Dr. Burlington. "Pursuant to the authority granted under the Medical Devices Advisory Committee dated October 27, 1990, as amended April 20, 1995, I appoint the following people as voting members of the General Hospital and Personal Use Devices Panel for this Panel meeting on September 14, 1998," and that is Dr. Yadin David and Dr. Charles Edmiston.

For the record these people are special government employees and are consultants to this Panel under the Medical Devices Advisory Committee. They have undergone customary conflict of interest review. They have reviewed the material to be considered at this meeting and those are

the two items I had to read.

I will begin the formal introduction of the panelists for the 33rd General Hospital and Personal Use Devices Panel Meeting by having our Panel Chair, Dr. Elaine Hylek introduce herself and then as we go around the room have the rest of the Panel members please introduce themselves .

I forgot to say one thing. On the agenda of the Panel participants I did have Dr. Whitehouse listed as being here today, and he is unable to attend. So, go ahead, Dr. Hylek, sorry.

DR. HYLEK: My name is Elaine Hylek, and I am an internist at Massachusetts General Hospital in Boston. I am, also, engaged in active clinical research at the hospital and through Harvard Medical School with a master's in public health and epidemiology and biostatistics.

DR. DAVID: Good morning. My name is Yadin David. I am Director of Biomedical Engineering Department at Texas Children's Hospital and St. Luke's Episcopal Hospital in Houston, Texas.

MS . RYDER: My name is Marcia Ryder, and I am a nurse consultant and a doctoral student at the University of California, San Francisco in the Department of Physiological Nursing.

MR. ULATOWSKI: Tim Ulatowski, Division Director.

DR. PEARSON: Michele Pearson, medical epidemiologist in the hospital infections program at CDC.

DR. EDMISTON: Charles Edmiston, Associate Professor of Surgery and Director of Surgical Microbiology at the Medical College of Wisconsin.

MS. AVILA-MONGE: Margaret Avila-Monge, nurse practitioner in private practice and on the faculty at Family Practice Residency Program and other nursing programs.

MS. CHANDLER: Christine Chandler, nurse practitioner and faculty at Harbor UCLA, California.

MR. PALOMARES: Salvadore Palomares. I am Manager of Regulatory Affairs for ICU Medical. I am the industry representative .

DR. HYLEK: Thank you. Today the Panel will make recommendations to the FDA regarding classification of unclassified washers and washer disinfectors. We will now begin with the presentation from the FDA. As noted on our agenda there will be an opportunity for members of the public and members from the industry to address the Panel.

I would ask that all persons addressing the Panel come forward to the microphone and speak clearly as the transcriptionist is dependent on this as a means of providing an accurate transcription of the proceedings of the meeting.

We are requesting that all persons making statements either during the open public hearing or the open Committee discussion portions of the meeting disclose whether they have financial interests in any medical device company.

Before making your presentation to the Panel in addition to stating your name and affiliation please state the nature of your financial interests, if any.

Captain Barrett of the Infection Control Devices Branch of the Office for Device Evaluation will now present the topic of today's Panel for the FDA.

CAPT. BARRETT: Good morning. My name is Susanna Barrett, and I am a reviewer in the Infection Control Devices Branch. My task is to provide you background information on washers and washer disinfectors intended for processing reusable medical devices.

Washers and washer disinfectors are devices used to clean, decontaminate or disinfect and dry reusable medical devices. The washers and washer disinfectors can be electromechanical or microprocessor controlled and may have one or more cleaning and decontamination or disinfection cycles to accommodate a variety of reusable medical devices.

The washers and washer disinfectors may come in a variety of models or types, such as single or multi-chambered units, units with single or double doors, free



standing or wall recessed.

They have spray arms, nozzles and adapters for directing fluid flow onto the external and internal surfaces of reusable medical devices. They may, also, have multiple accessory inserts such as specialized trays and racks for processing a variety of instruments.

The washers and washer-disinfectors have preset cycles for cleaning, decontamination or disinfection and drying reusable medical devices with defined cycle parameters.

The types of devices that are processed in the washers and washer disinfectors include the so-called "critical, semicritical and non-critical devices. " The terms "critical, semicritical and non-critical" are based on Dr. E. H. Spauldin's classification system which is predicated on the relative risks associated with the intended use of the reusable medical device.

Critical devices contact sterile tissue or body spaces . They should be sterilized between patient use. Semicritical devices contact mucous membranes or non-intact skin. They should be sterilized between patient use, but if sterilization is not practical then high-level disinfection is appropriate.

Non-critical devices contact intact skin and should at a minimum be cleaned between patient use. During

the cleaning phase the washers, washer disinfectors may automatically dilute and dispense a cleaning agent or the user may be required to pre-dilute and add the cleaning agent .

The selection of the cleaning solution for the machines may depend upon the types of soils found on patient-contaminated reusable devices.

In some instances manual precleaning of patient contaminated devices may be necessary before placing them in the washer or washer-disinfector. The instructions for the reusable device may require disassembly, pre-cleaning and preconditioning because of complex device design. In addition heavy soiling of the reusable device may necessitate pre-cleaning prior to placement in the washer and washer-disinfector. The disinfection phase may either be a thermal process using heated water or steam or a chemical process using a liquid chemical germicide.

Factors that have an influence on the cleaning process include such items as the design of the washer and washer-disinfector, such as the location of the spray nozzles and jet, the quality of water, the quality and type of detergent used during the process, the washing, rinsing and drying methods, correct preparation of items before placement, time and temperature parameters and operator performance .

Cleaning is a critical step of any subsequent terminal process. Inadequate cleaning can negatively impact the effectiveness of a terminal processing step, such as sterilization or high level disinfection. In addition, inadequate cleaning can expose the health care user to disease-causing organisms.

Disinfection can be accomplished by either a thermal or liquid chemical process. The temperature range for thermal disinfection processes ranges from 60 to 95 degrees C. The microbicidal efficacy of the washer-disinfectors making decontamination claims can range from low-level disinfection to high-level disinfection depending on the defined process parameters of time and temperature. The effectiveness of a thermal disinfection process can be influenced by water quality, the reusable medical devices reaching and maintaining the necessary contact conditions of time and temperature and any residual bioburden remaining on the cleaned device. Thermal processes are usually suitable for heat stable reusable medical devices.

For washers and disinfectors with a liquid chemical disinfection cycle the selection of the liquid chemical germicide should be dependent upon the desired level of disinfection for the reusable medical device. Among the factors affecting chemical disinfection processes are effectiveness and stability of the germicide after reuse,

residual bioburden remaining on the cleaned devices, organic load within the germicide reservoir, dilution of the germicide during use, contact temperature and pH of the germicide and the design characteristics of the reusable device . Chemical disinfection processes are usually used for heat-sensitive reusable medical devices.

FDA has placed into several categories washers and washer-disinfectors that were in commercial distribution prior to May 28, 1976, the date of the Medical Amendments to the Federal Food, Drug and Cosmetic Act.

The list up there is the list of washers and washer-disinfectants that have been classified by regulations . Washers and washer-disinfectors intended to process only general purpose articles such as laboratory glassware, pipettes, bottles and containers are considered medical devices. They are, however, treated as general purpose articles exempt from registration under 21 CFR 807.65(c) and exempt from 510(k) requirements.

Washers for body waste receptacles are labeled only to wash and sanitize body waste receptacles such as bedpans. They have been classified as a Class I device under 21 CFR 880.6800 and are exempt from 510(k) requirements of the Act.

Ultrasonic cleaners and any cleaning solution which is used with the ultrasonic cleaners are to clean

medical devices by emission of high-frequency soundwaves. They have been classified as Class I devices under 21 CFR 880.6150 and are exempt from the 510(k) requirements of the Act .

Contact lens cleaners and disinfectors are used for the cleaning and disinfection of rigid, gas permeable and soft contact lenses. They have been classified as Class II devices under 21 CFR 886.5918 and 21 CFR 886.5925 respectively.

FDA considers washers, washer-disinfectors and disinfectors for flexible endoscopes as accessories to endoscopes . These are units that are dedicated solely to the processing of the flexible endoscopes. Endoscopes are classified as Class II devices under 21 CFR 876.1500.

Washers and washer disinfectors intended for processing reusable medical devices such as surgical instruments, lumen devices, respiratory therapy equipment and other medical devices are considered medical devices within the meaning of Section 201(h) of the Act. They were legally marketed medical devices prior to the enactment of the Medical Device Amendments of 1976. They were not included among the devices that were classified in 1980 by the General Hospital and Personal Uses Devices Panel. These washers and washer-disinfectors are not considered by the agency as accessories to reusable medical devices since they

are not dedicated to a single type of reusable medical device . Considering the washers and washer disinfectors as accessories to medical devices could result in the same washer and washer-disinfector being placed in all three medical device classes.

FDA, therefore, has treated them as unclassified devices until such time as they are classified by regulation, The agency has received at least seven premarket submissions for these washers and washer-disinfectors and has reviewed them in a manner similar to other Class II devices. The reviews focused on the following types of information and data: labeling, performance test data including physical performance test data, simulated use test data with actual devices inoculated with a known challenge, in-use test data with the washers and washer-disinfectors used in a clinical setting, toxicological evaluation of residues of any process agent, material compatibility, software and electrical safety requirements.

The FDA recognized that there was confusion among the regulated industry on whether these washers and washer-disinfectors are devices subject to premarket requirements of the Act. On June 2, 1998, FDA issued an industry guidance entitled Guidance Document for Washers and Washer-Disinfectors Intended for Processing Reusable Medical Devices clarifying the regulatory status of these

unclassified washers and washer-disinfectors .

In August 1998, the agency released for comment a draft guidance entitled "Guidance on the Content and Format of Premarket Notification 510(k) Submission of Washers and Washer-Disinfectors . " The draft guidance for these washers and washer-disinfectors incorporated the review criteria that was used to review the previous premarket submissions.

The draft guidance recommends the following types of information be included in a 510 (k) submission: labeling, physical performance testing, simulated and in-use testing with actual medical devices, toxicological evaluation of any process residues, software validation and electrical safety and electromagnetic compatibility requirements .

The information in the 1998 guidance is very similar to the information recommended in the draft guidance from automated endoscope reprocessors which was released in August 1993.

The agency had previously issued a guidance document on May 3, 1995, for cleaning accessories such as enzymatic cleaners, detergents and lubricants for the washers and washer-disinfectors . The guidance document states that if the labeling for a cleaning agent does not bear any claims that the cleaning agent will cure, treat, mitigate or prevent any disease or condition that the use of

the cleaning agent is critical to the performance of or dedicated to any specific device or that the cleaning agent will disinfect or sterilize devices, the cleaning agent will be treated as a general purpose article under 21 CFR 807.65(c) and exempt from premarket notification requirements of the Act.

Many European countries have developed standards for washers and washer-disinfectors. Standards development is progressing in the European Committee for Standardization, the standards development organization associated with the European Union. The International Organization for Standardization is liaising with CEN to develop international standards for washers and washer-disinfectors used to process general medical devices, endoscopes and bedpans.

The potential risks associated by these washers and washer disinfectors include increased risk of nosocomial infections if the devices fail to perform adequately. The washers and washer disinfectors can fail to clean adequately devices with complex designs or heavily soiled instruments prior to a terminal process such as sterilization. Improperly cleaned devices may negatively impact the effectiveness of a terminal process. Processing in the washer and washer-disinfectors, alone, may be the terminal method for some reusable medical devices. Failure of the



washer and washer-disinfector to achieve the cycle parameters for the terminal process may result in the use of improperly decontaminated or disinfected medical devices. These failures may not be detected prior to the use of the processed medical devices on patients.

Other potential risks include incompatibility of the reusable device with the cycle parameters of the washer or washer-disinfectors resulting in damage to the reusable medical device, exposure of patient and health care user to chemical residues remaining on reusable medical devices from washer-disinfectors with chemical disinfection cycles, electrical hazards such as electrical shock to the user, electromagnetic interference with electronic components of the washer and washer-disinfector resulting in firmware failures, software failures, release of toxic fumes from washers with a liquid chemical germicide disinfection cycle and burns caused by exposure to hot water or the liquid chemical germicides used in the disinfection step.

The Panel is being asked to recommend an appropriate classification for washers and washers-disinfectors intended for processing reusable medical devices.

A proposed definition for these unclassified washers and washer-disinfectors is a general use washer or washer-disinfector is a device intended for medical purposes

to clean, decontaminate or disinfect and dry reusable medical devices.

The Panel is asked to consider the following: Is it appropriate to have one class for washers and washer-disinfectors that is independent of the types of reusable devices processed in the washers and washer-disinfectors?

Alternatively, should there be subclasses of washers and washer-disinfectors dependent on the types of claims and/or types of reusable devices processed? What are the specific device subclasses that you would recommend for each class?

Finally, what criteria, if any, would **you** recommend if washers and washer-disinfectors were classified under one class or subcategorized according to claims and/or types of devices processed? These recommended criteria could be items such as special controls. Examples of special controls include 510 (k) guidance documents, FDA recognized voluntary standards, labeling or postmarked surveillance.

Thank you.

DR. HYLEK: Thank you for your comments.

Are there any questions that the Panel would like to ask Captain Barrett?

DR. DAVID: I have a question about definition. Can you clarify if the definition includes all the

parameters or it can be a part of the, what is the definition? Specifically I am looking at the drying cycle. Are you including that?

CAPT. BARRETT: I am not quite sure I am following your question. The proposed definition that we have?

DR. DAVID: Yes.

CAPT. BARRETT: And whether it includes the drying cycle or whether it can just include clean and decontaminate or disinfect?

DR. DAVID: Right, yes.

CAPT. BARRETT: We included drying in the proposed definition because in many of these processes it is continuous from beginning to end where you start in clean and end up with a reasonably dry device. So, for consistency sake, because it is not quite sure where to draw a line between how to -- we have just done the whole thing, to include the entire process.

MR. ULATOWSKI: The device may have some or all the characteristics defined in the classification. If it did not have a certain aspect of a process then it could still fall within the definition.

DR. DAVID: Yes, that is exactly what I am trying to determine.

CAPT. BARRETT: It is a broad, general definition.

DR. EDMISTON: In our thought processes we are

just going to be contemplating reusable devices, correct?

CAPT. BARRETT: Yes.

DR. EDMISTON: So, we shouldn't even fall into mind the issues that are evolving daily on the reprocessing of single-use items by these devices?

CAPT. BARRETT: That is probably appropriate for another Panel meeting.

MR. ULATOWSKI: I would concur. That is certainly a controversial area and certainly an important area for discussion, but it is not part of today's discussion of this particular classification, but it raises an interesting issue for discussion in the future.

DR. EDMISTON: Because it may impact on reclassification of these devices again.

MR. ULATOWSKI: It may have an impact as things develop over time as things are going these days but for the time being this is the definition as we have proposed.

DR. HYLEK: Any other questions for Captain Barrett?

Okay, thank you.

We will now proceed to the first open public session. If there are any members of the public who would like to address the Panel, please raise your hand?

Or any individuals from industry, also, desiring an opportunity to address the Panel?

Okay.

MR. ULATOWSKI: Dr. Hylek, if I might add with bringing this to the Panel we are trying to close the loop on the entirety of devices that are used in reprocessing of medical devices so that we are entirely covered in terms of classification and guidance for products, particularly as we enter this period now where we are, also, closing the loop on standards in regard to medical devices. One thing I was mentioning was a standard under development right now in Europe .

Not too long ago we had several gaps in the process of devices that were not subject to oversight, premarket oversight, the germicides, for instance, certain cleaners but this particular aspect in terms of preprocessing of devices deserves a comprehensive approach to regulation and guidance, and as we move forward I think we are still a little segmented in terms of how FDA has developed its guidance and some instructions and recommendations for testing and design, but we intend to, over time and very soon to try to harmonize and integrate the various types of guidance that we provide to the industry on the sorts of design and testing recommendations that they should proceed with.

It is a mixed bag and one product relies on other products. The sterilizer relies on the washers. The washers

rely on what people do before they are stuck in the washers. The reusable the device has its own labeling and instructions that people have to pay attention to or else everything else may not work. So, it is a combination of factors that we are trying and going to continue to try to integrate into a scheme of direction and testing and guidance that will be helpful to not only manufacturers but to users because I think users you know better than I are often confused or don't have a full picture of what to do quite often with certain devices. They come down to central services, and they don't know what to do half the time I think with some products, and so they follow a certain scheme and direction, and we are going to try to provide with the help of the industry and others a more unified guidance and direction in terms of labeling and other things to help users out and manufacturers.

DR. HYLEK: You may certainly come up if you would like to address the Panel at the microphone and state your name, affiliation and any financial interests.

MR. MUSCARELLA: My name is Lawrence Muscarella and I do research and development at Custom Ultrasonics. That is my only financial association. Two questions, the first one is a lot seems to have been done with regard to flexible endoscopes in this field, and if I am understanding this correctly it seems as if when I was reading this

everything I was reading was applying to flexible endoscopes . Yet we were saying we are exempting it. My question is cannot whatever is used in the flexible endoscope situation be used as a model for applying to any of these other devices? The guidance article talked about processing reusable medical instruments. Well, a flexible endoscope is a reusable medical instrument. So, I am not quite sure why we have gotten to far with flexible endoscopes but we are kind of asking these questions about other reusable medical instruments of which of course, flexible endoscopes is one. That is my first question.

My second question is a shorter one. We are talking a lot about washers and washer-disinfectors here and I am wondering why we are not talking about sterilizers and washer sterilizers as well and what overlap they might have; if that were another issue, what issues may come up with that that would be germane to the topics today.

DR. HYLEK: Dr. Ulatowski or some other expertise from Captain Barrett, if you would each of you want an opportunity to address that question.

MR. ULATOWSKI: Yes, I will address that. I would like to ask Susanna, also, Captain Barrett to respond. The purpose of this Panel meeting is to classify a certain type of device that we have characterized in terms of our proposal, and we mentioned early in Captain Barrett's

presentation that the flexible endoscope reprocessing devices were in our consideration already classified. So, they are not the subject of today's consideration.

Now , I think we properly identified a certain group of devices for classification today, but if there is a question about that particular grouping, excluding the flexible endoscope washers, if there is some clarification needed there then maybe we can talk about that, but those are off the table for today.

MR. MUSCARELLA: I guess what I am saying if I could just follow up for a second is they may be off the table but can they be used as a model with whatever infrastructure was developed for classifying them, can they be used for, I am presuming rigid endoscopes, for hybrid region endoscopes that have flexible distal ends to them that can be used in similar procedures?

MR. ULATOWSKI: You are saying the devices that are used for flexible endoscopes or in what terms of a model are you --

MR. MUSCARELLA: Whatever your guidance article is and whatever your classification is for flexible endoscopes, it is not clear to me why that is not just being applied to these other reprocessed reusable medical instruments.

MR. ULATOWSKI: I think as we have developed guidance for the washers and washer-disinfectors we have



taken our experience and history with certain 510(k) premarket notifications and applied that to our guidance and in I think many cases a lot of the recommendations in our guidance play along the lines of what we have been asking for or seeing for flexible endoscope washers, but that doesn't necessarily mean that would be, we wouldn't reach for the high end of data recommendations depending on what the intended use of the product was. SO, if there was another type of washer we may ask for a lessor amount of data depending on what type of device it was.

Yes, I think what we learned is a model for what comes, what has come forward in terms of our guidance, and maybe Susanna could talk more about that.

CAPT. BARRETT: The guidance for the reusable, for the washer, washer-disinfectors, the unclassified washer, washer-disinfectors is based on the guidance that we put out for the automated endoscope reprocessor. So, we have done that . The reason that these unclassified as I mentioned washers and washer-disinfectors are not considered as accessories to a medical device is because they are not dedicated solely to one type of medical device as the endoscope reprocessors are dedicated solely to the processing of flexible endoscopes and those reprocessors were considered as accessories to flexible endoscopes and as a result they are considered medical devices, and they have

the same classification as the flexible endoscopes which would make them a Class II device.

MR. MUSCARELLA: Okay, I appreciate your comments, and the second question was in the purview of our conversations today. Where do washers and washer-sterilizers fall into this whole scheme?

CAPT. BARRETT: Washer-sterilizers are part of the sterilizer classification.

MR. MUSCARELLA: Thank you.

DR. HYLEK: I would like to ask if Mr. Ursick would be willing to step up to the microphone from Steris(?) just so the Panel could have all of the information at our disposal and hear all different perspectives and viewpoints. It might be helpful if you wouldn't mind so that we can all hear it and share in your recommendation that you supplied the Panel members right before we started.

Thanks .

MR. URSICK: I am Raymond Ursick with Steris Corporation, and I have no financial interests in the company other than being employed by the company. We did submit some written comments to Martha, and it really wasn't too far off with what Susan has recommended, essentially that different classifications should apply to the use of the device which would be certain -- of course, endoscope washers fall under Class II for general purpose articles;

bedpans, etc., would be a lessor classification. We felt that that should fall under a Class I with perhaps design controls; if there is software associated with that, it would take on design controls and as I understand and probably surmise most of the devices do utilize design controls today or utilize software controls. So, probably design controls would apply, but actually I would recommend that the majority of the washers, washer-disinfectors which have been around for quite some time, and FDA and industry are intimately familiar with, would fall into a Class I category. If a washer or washer-disinfector takes on a particular claim for a particular device and FDA is familiar with the parameters of that device, it should take on the classification of the device as an accessory to that device, but I would recommend that the majority of devices fall into a Class I for general purpose surgical instruments, etc. , and I think that is pretty much the context of what we submitted as comments.

DR. HYLEK: Okay, any questions for Mr. Ursick from the Panel just to clarify different things.

DR. DAVID: I have a question about the user training as maybe one of the weak links in your recommendation. How would you address that?

MR. URSICK: We do provide or everybody does provide I would assume labeling specific to the device,

detailed operator's manuals and the majority of industry or companies do provide operator training courses either at the companies or at the facilities upon the installation of the device. That is generally how we have handled it.

DR. HYLEK: Go ahead.

MR. PALOMARES: With regard to the washer disinfection is the device intended to restore the reusable device to its original sterility level?

MR. URSICK: It really depends once again on the claim. If it is a washer, and they are claiming a terminal process then that would be the application for that device. Most washer disinfectors aren't claiming a terminal process. They are generally recommended for further sterilization. I think as Susan pointed and Tim or Mr. Ulatowski that if you cannot wash it, you cannot sterilize it and that is our concern right now.

DR. HYLEK: So, is that a standard disclaimer if there is something that does not pretend to be --

MR. URSICK: The washer is not a terminal process.

MR. PALOMARES: So, these devices are really intended to washing reusable devices that are --

MR. URSICK: It depends what the purpose of the device is. I mean if they are safe to handle, sometimes that is the claim. You are claiming a low-level disinfection which allows the devices that are washed and

disinfected to be safe to be handled by hospital personnel. Some are washed and a high-level disinfection would be then disinfected for use, whichever that application might be.

DR. EDMISTON: Let me ask a question because some individuals who don't interact with CS or are involved in operating them not be aware of the type of material that these devices attract. There is always a disclaimer in terms of the device, a reusable medical device, what it looks like prior to washing and disinfecting. For instance, orthopedic device that may have bone chips or other type of organic material you would never make a claim that following washing of these devices that this is a terminal process.

MR. URSICK: That is correct.

DR. EDMISTON: so, recommendations would be written into performance standard indicating a certain level of cleaning has to occur prior to that device being put inside the instrument.

MR. URSICK: That is correct.

MR. PALOMARES: As a follow on you had, also, made the statement that you need further processing for terminal sterilization then.

MR. URSICK: We don't make claims for the instruments being washed. That is up to the instrument manufacturer.

MR. PALOMARES: But these devices are intended --

MR. URSICK: What we do is according to our labeling make recommendations of devices that can be processed in those washers or washer-disinfectors. It is up to the manufacturer to validate and qualify their devices for that particular process.

MR. PALOMARES: I understand that, but please go with me on this just for clarification? If the manufacturer of the washer-disinfector is claiming that it can be used for reusable devices to what extent are they stating that this product has been sufficiently cleaned or disinfected for reuse?

MR. URSICK: I am not certain I am following you. Like I said, once again, washers are used for a particular application. It is up to the manufacturer to qualify them to ascertain and determine to what level they can be processed.

MR. PALOMARES: Okay.

MR. ULATOWSKI: I think one problem with these general purpose washer and washer-disinfectors is the issue of not being dedicated to a particular device. So when you do your testing and you set your end point expectations it is tough to say, "Well, given this type of process and these parameters we are going to end up with a device that has a certain level of cleanliness. " When you throw anything and everything in there it is hard to set parameters and

expectations, and so in the design of the washer and washer-disinfector you establish certain criteria that you think are going to handle the greatest extent of possibilities of devices that are going to be put in there, and on the flip side what Mr. Ursick was, also, playing on and alluding to was that the reasonable device manufacturer has a role here, too, to label their product appropriately and to say that with our device you can stick it in this kind of machine under these certain types of parameters, and it should come out okay.

so, it is a joint effort of the washer manufacturer to have certain parameters and to test their product under general sorts of conditions but, also, the reasonable device manufacturer specifically for their device to validate conditions that are appropriate for their device . It is a two-edged sword.

DR. EDMISTON: I think the problem with these devices is that you can have a wonderful device but if it is not used properly it is not going to be an effective device, and I think that is the role of the professional organizations that develop guidelines, practice guidelines, especially ARN or APIC(?) that see that these devices get used appropriately within their sponsored institutions.

MS . RYDER: So, there is no list per se of devices that would fit under each of these categories? It is

specific to the manufacturer and what they recommend? I mean is there a list of --

CAPT. BARRETT: What we have seen is that the labeling for these devices will identify a variety of products that can be processed and they will come in, and they will, also, have some special trays that are dedicated for certain types of devices. They will have trays that are set up for processing lumen devices so that they have the specialized hookups for directing fluid flow through internal channels.

They will, also, have trays that are designed for doing bedpans. So, the general use washer can do bedpans. It may wash the rigid endoscopes, the instruments that are used with a rigid endoscope. They may have specially designed trays and adapters for that, and then again it may, also, do other trays just for doing general surgical instruments, glassware. So, it is hard to draw a distinction or a line as to what the washer is used for because it can be used for a variety of purposes, and it is not dedicated just to one particular purpose, and it may have different cycles depending on what is being washed. It may have a cycle that is designed for doing bedpans and then again it may have a cycle that is designed specifically for respiratory therapy equipment, such as the bags and the tubing.

MR. PALOMARES: So, is FDA saying that the end



user is responsible for validating the use of the washer for their specific purpose?

CAPT. BARRETT: No, what we ask the washer manufacturer to do is to validate and do testing, performance testing for the cycles and to use examples of the type of devices that it recommends that are compatible with its device .

The reusable device manufacturer or the device manufacturer is responsible for saying that it is a device for doing specifics. If a washer manufacturer is saying, "I can process lumen devices, " then testing needs to be done with lumen devices to support that claim, not every lumen device that is out there but representatives of types of lumen devices that they say they can do.

DR. EDMISTON: I see as critical to this performance standards because if you look in reality, if you look at how infections occur and the role of CS it is very rare for a device such as your company manufactures or others to fail and be responsible for the infection. It is much more common for a breakdown in the education of the cleaning of the equipment to play some role in infection. So, performance standards are extremely important because we base those standards in part on how we develop our guidelines .

MR. PALOMARES: Where are the devices going to be

used? Are they for device restorers or central supply in a hospital facility?

MR. URSICK: Generally for the hospital.

CAPT. BARRETT: Are you talking about the washers? They may, also, be in some stand-alone surgical centers.

MR. PALOMARES: But they were not intended for the assistance of device restorers to use in restoration of reusable devices then?

CAPT. BARRETT: Are you talking remanufactures?

MR. PALOMARES: Basically, yes.

MR. URSICK: They could be for scientific use but I mean for the purpose of this Panel and the purpose of this discussion it is for health care use.

CAPT. BARRETT: It could be the same device if it is used in a laboratory setting would not be a medical device but once you start making claims for medical devices it becomes a medical device.

MS. RYDER: Would it not, also, be applicable to alternate care settings, long-term care facilities or outpatient clinics?

CAPT. BARRETT: Yes .

MS. RYDER: Because you said, "Hospitals."

MR. URSICK: Sure, health care settings.

CAPT. BARRETT: Health care facilities of any --

DR. HYLEK: I have a question just for my own

education about the Class I and putting a lot of these more general medical devices under the Class I. If you have a complicated tool that is used in colorectal surgery that is going to be placed in one of these washers, washer-disinfectors that is clearly going to be used in another body cavity, like currently what are we doing with those; they are basically put on the same setting as the rigid --

CAPT. BARRETT: They would --

DR. HYLEK: And are we safe putting those types of devices with that one classification, is that the best way to go? I mean just for discussion purposes, I mean we have such a gamut of devices to try to consider and weigh burden to industry and everyone else and I am just wondering.

CAPT. BARRETT: One of the drawbacks to trying that could occur is if you look at it in terms of the claims made for the product or the types of devices processed in the product you may have the same product in all three classes because if you are going to make a claim that you do general purpose articles I believe that it would be limited, the labeling would be limited to general purpose articles.

If we look at it as in terms of accessories to medical devices, then if you had a claim as an accessory to a more complicated device the washer disinfecter may possibly be kicked up into the next class such as a Class II, and if you should ever process a PMA or Class III device

in there you might find that you need a PMA for the washer-disinfector.

We, in our approach have tried to look at it as more general and come out with what we think would be an approach to cover all the bases and not be so unduly burdensome by looking at the device itself independent of any particular device process in it and what we have asked for in terms of performance testing is based on the claims being made for the product.

so, in terms of the testing that would need to be provided, it is dependent on what is made, the claim. If the claim is only for a cleaning claim, then that would be all that a manufacturer would be required to provide is data to support any cleaning claim that they make for the product.

DR. EDMISTON: In reality it would not be unusual for a device to on one hand be used for cleaning of glassware possibly and in some other cycle to, also be used for cleaning of trocar or some other type of material. Is that correct?

CAPT. BARRETT: Correct.

DR. EDMISTON: So, these instruments really are multipurpose; aren't they, these devices?

CAPT. BARRETT: Correct.

MR. ULATOWSKI: If I might add, you mentioned

performance standards and in terms of professional organizations and development of guidance which is certainly very important, and Captain Barrett mentioned that the emerging European standard, the international standards organization is working along with the Europeans on it, and that standard is split in three ways. It is split on the short end with bedpans, on the long end with endoscope washers and then there is a middle ground, the general purpose devices. So, there is kind of a harmony here in how we proposed it in terms of the products as well.

DR. HYLEK: I am, also, curious if anyone has any data about if the terminal process like how many, what is the real public health burden if an instrument isn't quite, I wouldn't use the word "sterilized" but disinfected through that terminal procedure if you then put it into the sterilizer; do we have data of colony counts on that instrument post the whole process? What is the real absolute risk opposed to sort of the relative risk of conferring, you know, highly resistant organisms? Is it high? Is it low? Is it in the middle? Does anyone have any of that sort of microbiology?

DR. EDMISTON: There is sufficient evidence that suggests if equipment is not cleaned appropriately that it can convey infectious particles especially if organic material is a residue on that surface, be it fat,

subcutaneous tissue. Overall, however, the onus has really been on CS, the personnel in CS to ensure that these devices are cleaned, working with the performance guidelines for the various devices that are available.

Again, in my 20 years of experience it has been rare that we have had this breakdown of equipment resulting in infection. It does occur, but quite often there is a problem with maintenance of the equipment. Quite often there is a problem with the cleaning of the equipment, in other words cleaning of the inside bins once they have pulled the devices out and, also, because, to be perfectly honest with you the people who are employed in CS are usually the lowest paid people in the hospital. With consolidation of many of our hospitals supervisory staff may be responsible for one or two units within the hospital. We as infection control practitioners and professionals have had to give special interest to this area to ensure that training levels stay up. That is why I see performance information extremely important because it functions as a guideline for us, but yes, your answer is infectious particles can be conveyed on surgical instruments or other type of instruments. That is why from an infection control perspective we are using more and more disposable items like bedpans and blood pressure cuffs and thermometers where we think there is a high incidence or potential for nosocomial

dissemination of some of these organisms.

DR. HYLEK: So, we would all agree that behavior is probably fueling a lot of the problem with microbial resistance which is unfortunately the one thing that we often cannot change, and we continue to try.

I would like to just share some recent incidence rates from Mass General Hospital as far as multiresistant organisms . We have a 15 to 20 percent incidence now of resistant pneumococcus. We have a 15 to 20 percent incidence of methicillin-resistant Staph. aureus, and we also, have a 3 to 5 percent incidence of vancomycin-resistant enterococcus, VRE, and from a clinician's perspective and the patient and nursing staff and everyone involved in patient care, the inefficiencies introduced into a busy morning rounding on a general medical service when you have to gown and glove and mask for, I am not exaggerating, about every fifth patient it is burdensome, and those rates of gowning go up, I would almost want to use the word "exponentially" when you go to step-down rehab hospitals where those are the population of patients that are really just in and out of the general hospital, sick patients and almost every other room has some. Now , what component of that could possibly be eradicated with looking closely at this issue today I am not sure. I am curious, Dr. Pearson, of CDC, do you have any thoughts with your

background?

DR. PEARSON: I think my experience is that antimicrobial resistant pathogens, just like most other nosocomial pathogens are spread via the hands of health care workers as opposed to being primarily device related. so, I think in terms of what we are talking about today that would not be a major contributor in terms of nosocomial outbreaks or nosocomial transmission of -- I mean there is always the exception, and there is always the rarity, but I think most of the pathogens you have alluded you to come to or result from sort of just fundamental breaks in infection controls, you know, not inappropriate hand washing or inappropriate use of barrier precautions.

DR. HYLEK: If there are any other comments for the Panel we have a few moments, but I must request that you approach the microphone for the benefit of our transcriptionist and please state your name, affiliation and any financial interests you might have?

Thank you.

MR. CAINE: My name is Michael Caine. I am a market manager for Geninger-Castle (?) . I have no financial interests other than being an employee of the company. The terms "low-level, intermediate-level and high-level disinfection historically have been defined or meant by chemical means, and I would like to know if the FDA is going



to provide any guidelines for this related to thermal, moist heat as opposed to chemical because there is quite a bit of confusion there, and also, I would like to know I guess how the FDA would differentiate between washer and washer-disinfector?

CAPT. BARRETT: I will start with the second one first . A washer is a device that only makes a cleaning claim. It would not make a disinfection claim. A washer-disinfector would make a disinfection claim. It could be decontamination or it could be up to higher degrees.

MR. CAINE: I believe that is where I am trying to go. I don't know what those definitions are.

CAPT. BARRETT: A washer would simply say that it cleans the device.

MR. CAINE: But in doing so, if it removes all bioburden then it could be high-level disinfectant.

CAPT. BARRETT: But it would not make a high-level disinfection claim.

MR. CAINE : Okay, so, I could submit as a washer but still do higher level?

CAPT. BARRETT: You could submit as a washer but the labeling for the product could not make any disinfection claims for the product.

MR. CAINE: Okay, and related to thermal guidelines?

CAPT. BARRETT: We have tried to be consistent across the board in terms of what we look at when we look at disinfection claims regardless of whether it is by thermal or a chemical process. So, we use basically the same --

MR. CAINE: Criterion?

CAPT. BARRETT: Criteria.

MR. CAINE: Okay, thank you.

DR. HYLEK: Is that it for comments, questions?

So, why don't we adjourn at this point for lunch, and we will reconvene in this room at one-thirty.

Thank you.

(Thereupon, at 12:12 p.m., a recess was taken until 1:32 p.m., the same day.)

AFTERNOON SESSION

1:32 PM

DR. HYLEK: Before we broke for lunch you will all remember that I had asked a question if anyone had any data that would help us with the actual public health risk of the washer disinfectants and what the colony count load might be on instruments after the process, and I was wondering if Mr. John Friend could share with the Panel and everyone here the data you have?

MR. FRIEND: My name is John Friend. I am Vice President of Regulatory Affairs for Advanced Sterilization Products, a company within the family of companies with J&J, Johnson & Johnson, and I am a stockholder within that company.

In response to Dr. Hylek's comment about published data dealing with bioburden post washing in two recent articles that appeared in AJIC, American Journal of Infection Control, one written by Ratolla et al and the other one from Chan Myers et al, they referenced that type of data. They did not equate nosocomial infection rates, but they did talk about reserve organisms, microbes that were present pre-washing and then they did speciation post-washing and I am not here to offer any type of expert commentary or testimony on these articles but rather to address a comment that you had made, Madame Chairman.

DR. HYLEK: Are there any more comments from

industry?

No? All right, anyone else wishing to address the Panel before we begin?

Okay, we will now begin our Panel deliberations to classify washers and washer disinfectors. Any members of the Panel that have questions should indicate what information they require during these proceedings. We have forms for classification for each individual Panel member and one form that is to be completed when the final Panel recommendation is taken after the Panel has voted.

I would like to have Dr. David assist as moderator for this portion of the Panel deliberations due to his recent experience with the Classification Panel.

Dr. David?

DR. DAVID: Thank you, Chairman. What I would like to help the Panel to do is to continue the open meeting at this session and to go through the charges that were provided to us, those three charges addressing the issue related to the document that we have to vote on, and we will start with the first question that they asked the following information: Is it appropriate to have one class for washers and washer-disinfectors that is independent of the types of reusable devices processed in the washer and washer-disinfectors?

What I would like to ask the Panel is to

contribute their angle as far as what they are aware of or learned from the data presented to us.

Would anybody care to start with an opinion?

DR. EDMISTON: If we look at the distinction between a washer and a washer-disinfector the claim per se of a washer is that the item, device, whatever is being placed inside that is being cleaned to a specific level that may involve removal of organic material or whatever. There is no claim for disinfection or sterilization.

My question is should we separate washers from washer-disinfectors and look at washers as a separate entity for classification?

DR. DAVID: And the argument?

DR. EDMISTON: The argument would be that washers as I perceive them would fit easily into Class I as opposed to washer-disinfectors because the premise is that we are removing contamination, thereby potentially reducing the risk into a higher category, Class II.

DR. DAVID: So, as you look at the risk/benefit by definition you are saying that we have actually the possibility for one or two classes and if we separate those two devices out, we will be addressing a different level of requirement .

DR. EDMISTON: Of risk, of intrinsic risk.

DR. DAVID: Okay. Any additional opinion or

support?

MS. RYDER: I guess your one word that you just made seems important in that you are indicating that there is an intrinsic risk rather than a known risk, and Dr. Pearson commented earlier that from the CDC's perspective that a majority of nosocomial infections do not come from medical device related directly but from hand transmission. Do we know what percentage of nosocomial infections occur because of this type of infection? I mean what is the risk?

DR. PEARSON: The brief answer to that is no, we don't know. I would say in a qualitative way it appears to be low. If you look at diseases and/or outbreaks in hospitals that have been attributed to improperly sterilized device in a washer that is not something we see or hear about much at CDC. So, can one say that the risk is zero? No. But how great the risk is, I don't think we can quantify that.

MS. RYDER: So, we are making a decision on a perceived risk.

DR. DAVID: And, also, perhaps it is an issue of expectation by definition with cleaning versus disinfecting. With disinfection you have higher requirement for scientific support of handling pathogens compared to washing.

so, in looking at the first question, what we hear from the Panel so far that there is an argument to

differentiate between the two categories of devices, the washers and washer-disinfectors based on claim made.

DR. HYLEK: I am curious about one thing. Are they usually the same instrument? I mean are like 100 percent of these units really washer with the disinfectant coming or does it make any practical sense to think of these in terms of two different entities?

CAPT. BARRETT: What we have seen is one unit that will come in with a cycle in which the rinsing stage will have parameters that could qualify as a disinfection step. so, the question becomes at what point do you draw the line between a washer and a washer-disinfector because it may be the same process all the way through.

DR. EDMISTON: And it depends on where it is placed. If it is in a CS, it is more than likely going to be a washer disinfectant system as opposed to another facility that is essentially washing glassware from the laboratory, chemistry laboratory.

CAPT. BARRETT: It is the essentially washing laboratory or only washing laboratory glassware or what we refer to as general purpose articles then the washer is considered a general purpose article itself and would be exempt from 510 (k) requirements.

DR. HYLEK: When you say, "General purpose, " can you just iterate a list of what would be like glassware?

That seems --

CAPT. BARRETT: Glassware, test tubes, pipettes, Petri dishes, bottles, those types of items, items that you might find in a research laboratory.

DR. HYLEK: Without infection transmissible risk then.

CAPT. BARRETT: They are not medical devices. They are not used on patients. So, we wouldn't consider them as a medical device.

DR. HYLEK: So, just, I guess that we are clear on what our tasks are we are really sort of looking at the washer disinfectant?

CAPT. BARRETT: You are looking at a machine that would be used to clean, decontaminate or disinfect, dry medical devices, and medical devices would include surgical instruments . It could include the rigid scope. It could include respiratory therapy equipment. It could even include bedpans. These devices aren't dedicated to a particular type of medical device. They are used for a variety of devices. It is like your dishwasher at home I guess is the best I can do. You can do your, some of them may be designed to do a cycle for your crystals and your china, and you may have a different cycle just to do your regular glass, your everyday dishes and stuff, and that is the closest analogy I can come to how these devices are



used.

DR. EDMISTON: I guess the issue is since we know these are multipurpose devices and we don't know what the potential end use is going to be, then there is a high probability that a single device, washer-disinfector may be used to clean materials that have a low intrinsic risk as opposed to materials that might have a high intrinsic risk.

DR. DAVID: That is why I thought that what we are progressing towards is a claim-based differentiation between the two. What is the claim you made for the washer versus disinfectant?

DR. HYLEK: Right . I think we are all comfortable if it was a, you know, lower risk of transmission of infection, not, you know, being in one of these critical areas, you know, luminal or body cavity mucosal surface that we would be comfortable with just one class, Class I, but you know what is the best route to take if you are trying to encompass this broad spectrum, and what is the best way to go?

DR. EDMISTON: I would agree with you on that perspective .

DR. DAVID: And if you take the washers out, then you are focusing on the specific class of devices that not necessarily do you need to drag washers into.

MS. RYDER: Dr. Edmiston addressed this morning

that in his feeling the real issue was one of performance standard as to whether the efficacy of these was real or not . Is it possible to put them in a Class I with some performance standard regulation? If we did that, what would we be missing? What regulatory aspects would be missing by not putting them in Class II that would make a difference?

DR. DAVID: Let us go through the questions if we can because I think this would fall into one of the following questions we are having. I just want to make sure we conclude on the first and move on to the second and third.

Yes?

MR. ULATOWSKI: We can answer that question before moving to the questionnaire. The Class I designation relies upon as the questionnaire will indicate to you general controls as the means to ensure the safety and effectiveness of the product which includes quality systems, regulations, a good many factoring practices, for example, certain records and reports requirements. You had the training this morning about general requirements.

Class II is where the special controls kick in. If you believe that through your answering the question you believe that safety and effectiveness will be ensured, with the use of special controls then that leads you in another direction towards Class II. Special controls consist of,

may consist of guidance documents or standards or other sorts of controls that will be discussed in your questionnaire. So, it depends what you in your examination of, first of all the question is are you going to be lumpers and splitters and then secondly, what degree of control do you need in terms of ensuring safety and effectiveness?

DR. DAVID: If I am not wrong in the presentation this morning there was a possibility for a Type 1 class with some special controls.

DR. PALOMARES: No, there is actually, for Type 1 industry would be obligated to submit a 510 (k) if it wasn't exempt from 510(k) . They would have to follow quality system requirements. They would have to follow complaint handling, etc., but there wouldn't be any performance on the device per se. It would be mainly just general controls that all manufacturers have to follow.

so, if we want to put special controls, special labeling guidance documents that would default the products to a Class II designation.

DR. EDMISTON: So, efficacy would have to denote some performance, wouldn't it? To determine the efficacy of an item you would have to have some baseline performance to validate that efficacy. Is that true?

MR. ULATOWSKI: Performance comes in in two different respects depending on the degree of control you

want . Performance can come in, for example in terms of a special control where there is a voluntary consensus standard or there is a guidance document which outlines in terms of the guidance document a recommendation in terms of testing and performance. In terms of a voluntary standard it may outline certain performance criteria.

Performance, also, come into play though in Class I under design controls where you have an expectation to understand the design requirements for the products and you have designed the product accordingly and you have tested it accordingly. So, even in Class I there is an element of performance inherent in that level.

MR. PALOMARES: So, are we really talking about intended use for the device if we are just saying that it is intended to be a washer and then if it is a washer-disinfector it is a different intended use?

MR. ULATOWSKI: That is for the pleasure of the Panel to decide whether you want to, as I said, lump or split in terms of the control necessary to ensure safety and effectiveness for the products.

DR. HYLEK: It would seem if the manufacturer is claiming disinfection that that seems to raise if that is the claim being made, I could easily see that being a Class 11, if you are saying that you have a terminal process. So, a washer wouldn't really fit into that definition. I mean

they are saying, "We wash. We don't wash and disinfect. "

MR. PALOMARES: And that is how industry is looking at it. The control should match what level of control is necessary. So, if you are just washing a bedpan per se it should have general controls. If you are saying, "We are going to disinfect it to a certain level," then yes, you should have some sort of performance expectation, such that you would have to show that your washer disinfecter would remove a certain level bioload on the product.

DR. HYLEK: So, if we want to feel confident putting in a surgical clamp from a colorectal surgical procedure that is going to be thrown into the same unit in the basement that everything else is going to be thrown into, then we are going to have to assume and cover that higher risk instrument I would think to protect patients and so it seems like we are moving toward Class II for the disinfectant .

MR. PALOMARES: For the disinfectant I would concur that it should be more along the lines of a Class II but for a straight washer more likely general controls Class I.

DR. DAVID: So, from just summarizing the progression of the Panel discussion, therefore, the first item in the first charge to the Panel I would like to verify that we have reached an agreement as to the

appropriateness of having one versus multiple classes for washer and washer-disinfectors, and what I hear the Panel is suggesting is that we are recommending that there will be a separate class for washers than for washer-disinfectors; is that correct?

MS. RYDER: I agree.

MR. ULATOWSKI: I might add that in a final rule, a final regulation for a washer or washer-disinfector it might be described in a certain way as we described it under the definition and then can they within the same regulation be split into two parts which we have done with many devices. For example, the definition might say what the definition says as Susan presented to you. A washer, washer-disinfector is to wash and disinfect and dry reusable devices and then it may subcategorize within that regulation to say, A, if it washes is intended to wash devices it is Class I. B, if it is intended to wash and wash disinfect devices it is Class II. I am just playing out the way it might be described in the regulation.

DR. EDMISTON: That seems very reasonable.

MS. AVILA-MONGE : Which is actually the first two questions up there. Then it would be a yes to No. 1. It would be appropriate to have one class and then go down to subclasses within that class.

MR. ULATOWSKI: It would be one regulation.

MS. AVILA-MONGE: One regulation with two subclasses is what you are describing.

MR. ULATOWSKI: That is one option.

MS. AVILA-MONGE: So, it would be one class with subclasses .

MR. ULATOWSKI: It would be one regulation with two subclasses.

MS. AVILA-MONGE: With two subclasses, and the subclasses then would handle the wash versus washer-disinfector?

MR. ULATOWSKI: If that is the pleasure of the Panel to do it as an option that way.

MS. RYDER: Just as a point of clarification and forgive me if it has already been made clear, but I am still a little confused. Is it possible for me to go and buy a washer that only does that and then be able to buy something else that does both?

DR. DAVID: First of all, let me answer that as a user I can go and buy a washer, certainly, yes, and the other issue is that we don't know if tomorrow you might have more options like this, and I feel that based on the scientific evidence that there are two level of performance that we are talking about here, and we leave that opportunity for industry to claim one versus the other.

MS . RYDER : Thank you.

MR. ULATOWSKI: I couldn't see one that used the germicide to have a, I mean it wouldn't play out that it would have a washing claim because of the germicide being there, but thermal process there is a possibility.

CAPT. BARRETT: I think it might depend, also, upon the temperature range of the thermal process as to whether it is just a washer or whether there may be some implied claim of disinfection, also, because of the contact conditions for the rinse cycle or the cycle parameters that that would lead someone to think that there is, also, in this washing claim an implied disinfection claim, especially if the rinse cycle is running somewhere between 90 to 95 degrees C for 2 or 3 minutes which if I remember correctly are the disinfection claims that are listed in some of the European standards and the cycle parameters for disinfection that are listed in some European standards, I think the German standard and maybe, also, the Swedish

MR. PALOMARES: But as long as the manufacturer doesn't claim it as a disinfectant --

CAPT. BARRETT: If they don't claim, imply explicitly or anything then it would be a washer, but there could be in terms of how they presented the product it would have to be presented only as a washer, but I would, also, like to remind the Panel that the washing is your first step. So, how well you clean a device may impact any other



steps down the line.

MS. AVILA-MONGE: So, if you follow that logic, then it would seem that it would lead us still to look at one regulation with subclasses in order to differentiate the details of the possibilities?

CAPT. BARRETT: You could do that if that is the way the Panel wants to go.

MR. ULATOWSKI: It is our role at FDA not to make the recommendations. You are to make the recommendations. We will bring you to water, but you have to make the choices,

MS. AVILA-MONGE: My fear in breaking it up into two classes as was originally suggested, washer versus washer-disinfectant and then going into each of them, I think there might be some overlap that if we handled it by one regulation and then the subclasses within it we might be able to better define the details for the possible variations a little easier than going with two regulations or two **classes**. I am trying to think through the process.

DR. HYLEK: It is just hard in my mind to equate beakers and glassware and pipettes that really don't have a lot of infection-transmissible risk with, again, using the analogy of hemostats in surgery where it doesn't seem to be quite the same as thinking of one in terms of Class II, the bedpan or the beaker opposed to if there is clearly a claim

that states, "We are very confident that our terminal process is going to give you the most effective pre-stage to sterilization, " that that is a pretty lofty statement and there should be some more, I would think more stringent standards to make sure that is the case as opposed to making everyone no matter what their washer was intended to do without the disinfection part of it.

CAPT. BARRETT: Again, washers that are dedicated to general purpose articles are exempt and bedpan washers have already been classified as Class I and are exempt. So, if they are dedicated solely for those particular items they are exempt. When they are used for **all** types of devices including the more complicated devices, then they lose the exemption, say, for general purpose washer, if you include medical devices into that, into the labeling or infused in that washer or washer-disinfector.

DR. EDMISTON: I don't see any problem. Are we having a debate on the class between Class I and Class II because I don't really see any distinction here. I see these washer-disinfectors as being intrinsically placed in Class II because of the kinds of materials that are going to be used in them. I don't see any distinction between a hemostat or any other type of surgical or medical device that may have been used to examine a patient or penetrate some body cavity.

DR. HYLEK: I agree with that. Since Captain Barrett just informed us that if it is not an actual medical general purpose it is already exempt. So, the bedpan is already exempt. So, that example of the general purpose is already off the map. So, it sounds like we are talking about medical instruments, devices which seems --

CAPT. BARRETT: The thing is if the washer can have accessory trays, racks, you may process bedpans in this washer; you may, also, process hemostats in this washer. You may, also, process general surgical instruments, lumen devices, respiratory therapy. These are used for such a wide variety of different types of devices that there will, in fact, be overlap between some that one time if they limited the claims would be considered exempt but if they add more stuff, more types of devices to it then they lose the exemption. So, the question then becomes what does the Panel recommend that we do.

DR. DAVID: So what we seem to be avoiding is having a laundromat down in CS where you have different machines for different devices because that wouldn't be the practice.

DR. EDMISTON: I don't think we can differentiate how these devices are going to be used. So, this issue of washer, washer-disinfector is irrelevant. I think we are talking about washers-disinfectors and in that case my

personal belief is that these are Class II devices.

DR. DAVID: So, if we go to our original synopsis it might be that we said that washers and washer-disinfectors can be in one regulation and two different classes, washers in one and disinfectors in another.

DR. EDMISTON: So, we are saying that everything would be Class II. Let us put a number out there. So, everything is Class I or Class II?

DR. DAVID: Everything as far as washer is a class that we haven't decided, but let us say for these purposes it is I and everything that is disinfecting is Class II.

DR. EDMISTON: You see the problem that I have is that we don't know how these devices are going to be used, and industry is going to have to make some claim pursuant to the class we put it in.

DR. DAVID: Then I follow what you are saying, and I think that what I would like to do is poll the Panel and see how would you like to recommend that we will do that, realizing that we are talking about general purpose articles to be cleaned and/or disinfected. Do you want to have one regulation with one class or one regulation with two classes or two regulations? In other words, washers and washer-disinfectors should be in the same single class?

DR. EDMISTON: As I understand what the question posed before this Panel is we have one regulation, should

there be one class or two classes, not whether there should be two regulations altogether and as a Panel we have to look at what is the risk/benefit from this. Really for a washer we are not expecting any reduction in microbial load. We are just saying that it will clean the thing and for a disinfectant we are saying that it will reduce it to a certain extent. It is not terminal. We agreed as a group I believe earlier that there is still terminal sterilization that can occur later on.

MS . S CHULMAN : May I say something? Marjorie Schulman. With the 510(k) stuff I just want to get you off track on one thing. The one regulation with two subclasses or the two regulations is really just housekeeping for us. So, please don't get hung up on that because there are many regulations that are divided into two parts and then there are many that have just a different CFR number.

DR. EDMISTON: Could you do me a favor then? Could you interpret for me what I had said earlier under that presence?

MS . S CHULMAN : I think you are on the right track. Your question is do you want to have, and let us just call them regulation. If you want to have one regulation for washers and one regulation for washer-disinfectors, you would go through those sheets that we went over this morning twice, one for the washer, one for the

washer-disinfector and see where you come out for both of them. You may find that they both come out in Class II. You might find out they both come out Class I, one or the other. So, I think that is your question there, how you want to split.

DR. EDMISTON: I guess the question I had, is it prudent to discuss washers as a separate entity since -- will washers actually be something that will be purchased as a separate entity that do nothing but wash? I suspect that is not the case or am I wrong?

MR. PALOMARES: I think you may be mistaken on that simply because you could just wash bedpans. You don't need to disinfect them, and if you needed to disinfect or sterilize a device, whichever you wash, you can use something as a steam sterilizer or --

CAPT. BARRETT: I don't know that that is true. You have to remember that as you are washing you may be mechanically removing bioburden and there is in the process of washing a reduction in bioburden, not only microbial but, also organic. So, it becomes a little bit at what point does washing stop and you start hitting disinfection, starting with the lowest level of decontamination and then going on, and again, sometimes some devices processing in these machines may be the only step that you need to do, and even if it is just cleaning has the device been adequately

cleaned to make it safe to handle; are the parameters of the washing cycle sufficient so that when a health care user picks up the device for whatever purpose, even if it is a terminal processing, the cleaning step has been adequate to make the device safe to handle.

MR. PALOMARES: But that all relates to the claim that the manufacturer submits with the device.

CAPT. BARRETT: They may still only make a cleaning claim for a semicritical or critical device which is to be terminally processed with another step.

MR. PALOMARES: And that is okay as long as you are saying that it is clean. If you are going to clean it, but you set it up such that the process can actually sterilize it, well, then the manufacturer is just shortchanging himself.

CAPT. BARRETT: We are not talking about sterilization.

MR. PALOMARES: Disinfect, excuse me.

CAPT. BARRETT: Disinfection.

MR. PALOMARES: You can overkill on developing a product to clean it to the point where it can disinfect, but as long as you claim that it is used as a cleaning device that is all it can be used for.

DR. EDMISTON: You see, from a microbiological perspective when we say that something is clean, we don't

discuss the word "disinfectant" or we don't say, "It is sterile." We say, "It is clean." And what does clean mean? Do we attach a performance standard to clean? I think this is a germane issue. I don't think we want to get involved in that issue.

DR. DAVID: The point I think that Salvadore is making is that it is the claim that we based upon what is the claim of the manufacturer for this device, if it is to clean versus is it going to be disinfecting.

DR. EDMISTON: I understand that.

DR. DAVID: So, what I would like to do is to see if we can reach an agreement among the Panel as to how we want to handle that realizing that we went around the issue of regulations and classification and now we are at the point where we understand that the question, are we dealing with washers as an entity versus washer-disinfectors as an entity or do you want to lump the two together. That is the question.

so, let us -- you are smiling.

DR. EDMISTON: I will let somebody else start first .

DR. PEARSON: Are we taking a poll? I will start. I say lump them.

DR. DAVID: Okay.

DR. EDMISTON: I am inclined to lump them, too,



into one class.

MS. AVILA-MONGE: I do, also.

DR. DAVID: Do?

MS. AVILA-MONGE: One lump. I am a lump.

MS. CHANDLER: I agree to combine them.

MR. PALOMARES: I believe that we should separate them into two different classes.

DR. DAVID: Okay. Marcia?

MS. RYDER: I will lump as well. Could I say that with a caveat?

DR. DAVID: Sure.

MS. RYDER: I thought what I heard earlier was that if I buy a washer that the only thing I am going to use it for would be general use items or bedpans, but --

DR. DAVID: No, that is separate.

MS. RYDER: Okay, those are already exempt. So, what would I be purchasing a washer for that I would use only a washer and not a disinfectant for that isn't in those two categories?

MR. PALOMARES: I believe previously you had devices that were classified as accessories to those. So, a washer for a bedpan would have its own classification. What they are taking out and please correct me if I am wrong is that they are just taking the full gamut of all general devices. There is one washer for that.

DR. PEARSON: It seems to me that the exemption is already in place for general purpose items which are non-patient care type items and, also, non-critical items like bedpans. So, basically we are talking about something to clean a semicritical or critical device which to my way of thinking that should be at least a Class II. I mean we are not talking about non-critical devices, and we are not talking about non-patient care items. We are talking about something that is going to come in contact with a sterile body cavity or non-intact skin or a mucous membrane. Am I misinterpreting that?

DR. DAVID: No, you are doing fine, but let us move on here.

Go ahead. Can you identify yourself?

DR. LIN: Chiu Lin. I am the Branch Chief for Infection Control Devices Branch, ODE. It seems to me as I sit here listening to the Panel, it seems that it is kind of confused. So, maybe I would sort of repeat what Captain Barrett presented this morning. In the past the agency already has some classified washer and washer-disinfectors based on the risk of the device that it poses for someone. If it is a washer or washer-disinfector used just for laboratory glassware or so-called "general purpose" articles the agency has determined it is exempt from 510(k) .

so, if we use it just for body waste receptacle

then we have been already in the classification this is Class I exempt, that if this is just strictly for flexible endoscope we treat although it has not come through this Panel but we treat as an accessory to endoscope which is Class II. So, obviously that washer-disinfector we treat as a Class II device. So, right now remaining is the washer-disinfector used for any other medical device and that could be Class I. It could be Class II. It could be Class III, and so the Panel under this so-called "unclassified washer" and "washer-disinfector" whether that should be Class I or Class II or Class III. I think that that is the Panel's challenge, and one more thing I, also, wanted to clarify. Maybe for the same washer or washer-disinfectant there are probably several cycles that are up to the user to control. You can set up a cycle just for washing purpose. You can have a cycle you can set up both for washing and disinfection or you can just set up for disinfection. So, could be we have one machine that could perform all those function. So, you need to keep that in mind.

Thank you.

DR. DAVID: Thank you very much for the clarification. I will just throw my vote for a combined and the Chairman will vote if we just need to break a tie, I guess.

DR. HYLEK: I would, also, combine, leaning

toward Class II designation.

DR. DAVID: So, with that I would like to move on then, and alternatively should there be a subclass of washer and washer-disinfectors dependent on the types of claim and/or types of reusable devices processed? What are the specific device subclasses that you would recommend for each class?

so, if we combine those, the question now is what is the class for the device.

MS. O' LONE: If you take yes to No. 1, the question was asked should there be one class. So, if you don't say, "Yes," to one, then you would have an alternative. That is what we are talking about.

DR. DAVID: Okay, thank you.

MS. O' LONE: It is a little hard to write these questions.

DR. DAVID: So, the third item then is finally what criteria if any would you recommend if washers and washer disinfectors were classified under one class or subcategorized according to claims and type of devices processed? These recommended criteria could be items such as special controls, guidance documents, performance standards, postmarked surveillance, labeling, etc.

Should we go to the form at this point and start -

MR. ULATOWSKI: I just had a comment in regard to the third question on what criteria. It is kind of putting the cart in front of the horse a little bit. Certainly it is appropriate to reflect upon what sorts of measures are out there to control safety and effectiveness, but the question as worded kind of presupposes a classification, a recommendation has already been made to a certain extent. so, I would consider the question as pondering the sorts of controls that are out there but to move to the classification questionnaire to get down to a box in terms of class before you come to some qualification of them as special controls or whatever. Do you understand the gist?

DR. DAVID: So, what will be the next step then is to move on to the document and go through the questionnaire.

MR. PALOMARES: A point of clarification? If we are going to classify them all as one class does that eliminate the previous established classes like glassware washers as an accessory?

DR. DAVID: No. This is separate because we are talking about separate device categories.

MR. PALOMARES: So, this is strictly just for general purpose if it covers a full gamut of devices.

MS. O' LONE: I don't know if I can add some clarification to this or not but I will try. General purpose as you mentioned is a hard word to use here because

we have general purpose washers, and so we have kind of looked at the idea of a general use washer when we are talking about these because there are other uses besides what general purpose washers are and dedicated washers are. so, it gets a little tricky that way. That is one of the things that gets confusing. I am sorry.

DR. DAVID: Okay, we have two forms, one called the supplement data sheet and the other one general device classification questionnaire, and it was suggested this morning that maybe we want to do the supplementary first.

MS. O'LONE: We should do this one first.

DR. DAVID: Okay, and the Chairman would fill in one for the Panel or each one?

MS. O'LONE: There is a little bit of direction to the Panel, but for this particular part we talked about each person will have his own classification sheet to fill in, and that will be passed forward and collected and then as the final vote comes after we have gone through this we will make one final sheet that is the recommendation from you as a Panel that incorporates the final vote.

DR. DAVID: Okay. Ms. Schulman, please take us through the first two lines there?

MS. SCHULMAN: Okay, generic type of device, and I guess we have agreed that it is the washer and washer-disinfector. Is that correct? Correct me if I am wrong.

DR. HYLEK: I think that is correct.

MS. SCHULMAN: And the classification recommendation we fill in afterwards. Just a couple more housekeeping ones. Please remember that a medical device should be placed in the lowest class which will provide adequate controls to reasonably ensure the safety and effectiveness of the device, and questions 1, 2 and 3 pertain to the degree of risk of the device and can be answered broadly.

SO, question 1, is the device life sustaining or life supporting?

(There was a chorus of no's.)

MS. SCHULMAN: Do you want to go around?

DR. DAVID: I would suggest that if there is an exception to what we hear from the Chairman, then we will have a debate. Otherwise we will move ahead. So, on question No. 1, I heard no.

Question 2?

MS. SCHULMAN: Okay, question 2. Is the device for use which is of substantial importance in preventing impairment of human health?

DR. EDMISTON: Yes.

DR. DAVID: So, question No. 2 is yes..

MS. SCHULMAN: Okay, question 3, does the device present a potential unreasonable risk of illness or injury?

DR. DAVID: No.

DR. HYLEK: That is hard to answer because we don't really have the nosocomial infection rates of the particular units that we are trying to describe. So, it is hard to in some definitive way say, "Yes," or "No," and we don't really have the microbiology behind the --

DR. DAVID: If you use the device properly does it present an unreasonable risk of illness?

PARTICIPANT: No.

DR. DAVID: If you use it properly?

DR. HYLEK: It sounds like it should be no then.

DR. DAVID: So, the answer to three is no.

MS . SCHULMAN: No. 4, did you answer yes to any of the above three questions?

DR. DAVID: Yes.

MS . SCHULMAN: That is yes?

DR. DAVID: No. 4 is yes.

MS . SCHULMAN: Because we answered yes to No. 2, I believe. Okay, if yes, we go to No. 7. Is there sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness? First we answer yes or no to that, and then if the answer is yes, we go and list the special controls.

(There was a chorus of yes.)

MS . SCHULMAN: Okay, so the answer is yes.



DR. DAVID: The answer to No. 7 is yes.

MS. SCHULMAN: Okay, then it is classified in Class II and now is the time for that last question where you ponder to go through and we will name the special controls for Class II.

DR. HYLEK: In addition to naming would you mind if you have the expertise to describe actually what these would entail and what the burden to industry would be so that we can sort of weigh in on what seems reasonable, unless there is someone on the Panel because I don't --

DR. DAVID: You have all of Class I applied here, registration, record keeping, good manufacturing practices.

DR. HYLEK: No, I mean if you are looking at No. 7, what does performance standard entail? What does postmarked surveillance entail? What does the patient registry entail? What does the device tracking entail? You know, which of these, I don't think we can really check the appropriate boxes without really knowing what each one, how long it is in place, who enforces it, who checks it; you know, how does industry respond to all of these different --

MR. PALOMARES: Industry would respond to FDA for each of these items as stated. It is like postmarked surveillance. That is more along the lines of device tracking, and so they would have to be able to identify where their product is in **case** they need to be recalled or

removed from the market.

DR. HYLEK: So, that is the rationale for device tracking is mainly for recall, struts breaking off the clamshell for the ASD repair. I mean is it that type of thing? So, that doesn't really apply here. Okay.

MS. SCHULMAN: The second one, performance standards is, a performance standard is sort of rule making and there is a difference between performance standards and guidelines or guidances.

Go ahead, Tim?

MR. ULATOWSKI: Performance standards we are talking about regulatory standards which is a standard that FDA promulgates. Now, that is different from voluntary consensus standards such as ISO standards and AAMI standards of that type which can be special controls but are not the performance standards indicated there.

DR. DAVID: So, the question here is do we have voluntary guidelines or standards out there?

MR. PALOMARES: They are promulgating. If you remember early in the training that stated that ISO as well as CDN was developing standards along these lines. Those are voluntary standards, and what would happen is as manufacturers would submit a 510(k) for these devices if it does fall into the Class II, if industry is following those standards, FDA would expect the manufacturer to, also,

comply with those standards as well.

DR. DAVID: EPA or other agencies, do they have any --

MR. ULATOWSKI: Not specifically for these types of devices. The only standards as stated were the emerging European standards, and there are, also, other applicable standards like electrical standards and other standards that might apply, but they are all voluntary consensus standards that are --

DR. EDMISTON: Give me an example of a potential performance standard for a washer-disinfector? What would be a potential performance standard? Would it relate to the efficacy of the device?

MR. ULATOWSKI: Yes. The particular standard being developed that we have alluded to has design and performance criteria as part of the standard.

MR. PALOMARES: I think to help the Panel if you can give a sample of an existing performance standard versus what is a voluntary one.

MR. ULATOWSKI: There is only a couple regulatory standards that are on the books. So, that is a poor -- I cannot give you much there anyhow. There is a lead standard that FDA recently promulgated. There is another standard in the ventilator area.

DR. EDMISTON: But for a device to be

intrinsically called a disinfecting device there has to be some standard.

MR. PALOMARES: There are voluntary standards. That is different from a performance standard.

MR. ULATOWSKI: The regulatory standard I am talking about is FDA writes the standard.

DR. EDMISTON: So, what we are discussing is to propose to put in place then a standard, a regulatory standard for these devices, correct?

DR. DAVID: No, what we are discussing is do we need to incorporate either a voluntary-based standard that the Panel feels is satisfactory or to request the FDA to generate performance --

DR. EDMISTON: So, we can defer to what have been industry voluntary standards.

DR. DAVID: Yes .

MS. RYDER: So, if we check this box, performance standard, what does that mean?

DR. DAVID: That means that the FDA will have to write one.

MS. RYDER : And what do we check if we want them to follow the voluntary standards?

DR. DAVID: That is under others, unspecified.

MS. RYDER: Do we know whether the European standards and the ISO standards meet satisfactory criteria

for the United States?

MR. ULATOWSKI: That is part of the standards process. There is government participation on the ISO side liaising with the Europeans in the development of the standard that they are creating. So, we are observing and participating in that development, but it is not a regulatory standard. It is an industry slash voluntary government standard.

MS. RYDER: So, the ISO, has that already been done or it is in development?

MR. ULATOWSKI: No, it is in process right now.

MS. RYDER: We have not voted on it?

MR. ULATOWSKI: You may vote --

MS. RYDER: No, I mean the ISO.

MR. ULATOWSKI: No, it is not up for a vote.

DR. EDMISTON: My understanding is it is going to be years because they are looking at a variety of devices right now.

MR. ULATOWSKI: The way standards are it may take some time. You cannot anticipate this, but is appropriate for the Panel as panels have done in the past to make a recommendation that should such a standard come forward that it be a special control.

MR. PALOMARES: Furthermore if you look inside the packet that was sent to you on the guidelines that are being

developed right now, they do talk about certain levels of controls. They may not be regulatory standards or performance standards per se, but they are standards which FDA expects industry to follow.

MR. ULATOWSKI: I didn't follow that myself.

MR. PALOMARES: On the draft guidance that is in circulation right now the FDA has put in levels as residuals of chemicals, disinfectants remaining on the product.

MR. ULATOWSKI: You are speaking of our guidance document. The guidance document is a recommendation regarding evaluation of products that we have out for use by people.

MR. PALOMARES: But , also, it is showing basically the level that industry would basically have to follow for them to have their device cleared through the 510(k) process as well.

MR. ULATOWSKI: It is a set of recommendations, and if they have another opinion they can always present that, but that is our best opinion.

DR. HYLEK: Is there anything written now about some sort of bio-standard if the manufacturer feels that they have the best washer-disinfector that is coming on the market, you know, is it part of this 510(k) where they would put in some of their own internal testing to demonstrate that it really does indeed do what they are -- that is what

I am wondering, if the voluntary may be adequate and we could leave it at that, if you can at least give us some sense that there is some percentage killed or some terminology that is currently in use.

MR. ULATOWSKI: I will have to say that the jury is still out on precisely what is the set of criteria that products should meet in terms of performance, in terms of a standard and that is the current discussion ongoing now in terms of the standard that is being developed, but still I think there is a spectrum of tools that can be used to control the product under special controls. We can foresee certain standards coming forward that might be a tool, the guidance document perhaps as a tool.

In essence when one submits an application to us, a 510(k) they are attempting to show by certain tests and information that they are as safe and effective as what is currently marketed. So, that is the threshold for clearance, and if they do it using a standard, a voluntary standard methodology or if they use their own internal methodologies that might show equivalence, that is their option to do, to use those possibilities.

DR. DAVID: What, for example, would fall under the testing guidelines?

MR. ULATOWSKI: Our guidance is a set of recommendations, and we include a series of recommended

tests to show the mechanical cleaning.

DR. DAVID: That would be put forward to testing guidelines rather than others.

MR. ULATOWSKI: It would be under guidance rather than testing guidelines.

DR. DAVID: Okay.

MS . SCHULMAN : On patient registries you asked is it where the patient would have to register.

DR. HYLEK: So that is not really applicable here. What about postmarked surveillance? That is not really applicable either.

MR. ULATOWSKI: No.

DR. HYLEK: So, the only one it sounds like we are really talking about is other for voluntary standards that are hopefully going to be -- or we could ask that they be adopted once these other organizations come up with something that seems reasonable.

MS . SCHULMAN : Correct, and you can, also, add in anything that you feel that you want maybe. We are not talking about the guidance document but anything you want on record such as sterility, anything else. That "other" is a catchall phrase for --

DR. DAVID: We want to make sure that we address issues relating to user education. We felt that this was something that we are concerned about.



MS. AVILA-MONGE: Would labeling come into this as well at this point?

MS. SCHULMAN: Yes, anything that you would want in the labeling would go there.

MR. PALOMARES: SO, is this device intended for over-the-counter usage as well?

MS. SCHULMAN: That is not that question yet.

DR. DAVID: And when we say, "User education, " that will include maintenance.

MS. SCHULMAN: I am sorry, what?

DR. DAVID: The service people.

MR. ULATOWSKI: That could be yes, I mean you can recommend the extent.

DR. HYLEK: So, if the Panel would turn to what we were given this morning, the special controls Class II, there is a nice list that we can go through quickly I think just to do this in some expedited fashion. So, the performance standards I think we have already said that we don't want to have the FDA impose some regulatory standard. It sounds like we are going to have a voluntary standard and charge industry to adopt on a voluntary basis some national or international standard that hopefully will be coming down the pike. Postmarked surveillance, we already said that that is not applicable. User information and checklist, I don't think that is a big issue. That is basically telling

the guy at central supply that this is intended to disinfectant and these types of instruments would be -- does the Panel agree that that is a reasonable thing to request?

(There was a chorus of agreement. )

DR. HYLEK: It probably would be a paragraph. I don't think it would be burdensome.

Patient information and education doesn't apply.

Now , the guidelines and guidance documents, how does that fit into this special control Class II? HOW would we weave that in under the other?

MR. ULATOWSKI: We have included in your package our guidance for such devices. We don't have guidelines per se . Guidelines is a buzz word for a higher class of direct requirements for products. Rather we have guidance which is a softer form. It is a recommendation for a set of design and testing factors and that is what we have available at this point in time, a guidance. So, that would be the next item, the guidance documents.

DR. HYLEK: And the guidance document was released and it is out for 90 days for everyone to be able to render an opinion on it. So, we are sort of making a decision without knowing what is going to happen to that guidance document. Can you give us some advice on how to handle that part of it?

MR. ULATOWSKI: You may recommend that once

finalized the guidance be a special control.

DR. HYLEK: Okay, and that is out to the public and industry. So, it is very multidisciplinary. Does everyone feel that is reasonable?

(There was a chorus of agreement. )

DR. HYLEK: Patient registries we already said that this doesn't really apply. So, that leaves subject to 510(k) and design controls are the last, no, actually that applies only to class. Oh, on this list. SO, there are the last two and then hopefully we will be done with this section. So, they are already one there. Okay. What about this design control?

MS. SCHULMAN: All Class II devices are subject to design controls.

DR. HYLEK: So, that is automatic. Should we list it under other on this form? No. Okay.

MS. RYDER: May I play devil's advocate for just a moment on the voluntary standards? Since I am on the medical injections committee for AMI should the United States vote no on the proposed standards that come forward, what implications would that have to having them comply to those standards?

MR. ULATOWSKI: It would certainly put a damper on their applicability in terms of special control, but there is, also, the other aspect currently under the new law that

we have that I mentioned earlier, and that is the recognition process for standards.

If we believe a standard has value in terms of design or testing, then we will likely recognize it for use in the premarket review process, but a precursor to that would most likely be a positive vote on the part of the United States in regard to that standard.

DR. HYLEK: So, are the Panel members satisfied with that under other?

Should I just reiterate? Under other we will have voluntary standards, user information which might be in the form of a paragraph, just to reiterate to the user because we know behavior is the main player with nosocomial infection as well as a recommendation to adopt the recommendations within the guidance document that is currently out for review and comment.

MS.SCHULMAN : Okay, then you are going to like this part. We are going to get to skip questions 8, 9 and 10. We skip 8 because that only applies to performance standards and we go with the performance standard. We went with guidance.

Question 9 goes to performance standards, also. It is saying if you recommended for performance standards should it be in place before reclassifying the device, and the tenth question applies only to Class III. That was how

quickly would you want us to call for PMAs if we were calling for PMAs.

SO, on the back of that sheet there is more. Okay, Question 11A refers to restrictions such as prescription use or similar limitations as to the use of the device . This is a prescription question, and the question is can there otherwise be reasonable assurance of its safety and effectiveness without restrictions on its sale, distribution or use because of any potentiality for harmful effects or the collateral measures necessary for the device's use?

DR. PEARSON: Who wrote this?

(There was a chorus of no.)

DR. HYLEK: So, what is the intent of the question?

MS . SCHULMAN: The intent of the question is if you answer 12, it is not a prescription device and you are done -- I mean if you answer yes, then you go to 12, and we are finished with this now as a supplemental sheet. If you answer no, it is a prescription device, we go to 11B and identify the needed restrictions.

MR. PALOMARES: But we are talking about the issues with the training of people, personnel in CS, and when I look at 11B as used by --

MS . SCHULMAN: You only get to 11B if you answer

yes to 12, I mean to 11A.

MR. ULATOWSKI: Dr. David, in regard to that 11B persons with specific training I can see where that could be a little confusing, but in regard to prescription products it has only been used very sparingly in regard to physicians with particular training and expertise in very critical devices, and it has only been used a couple of times to my knowledge in cardiovascular devices for instance and not generally.

DR. DAVID: Thank you for the clarification. So, 11A the vote is for no need for prescriptions.

MS. SCHULMAN: So, the answer is yes. Is that backwards enough for you?

Since the answer is yes, we are done with that sheet .

Okay, the supplemental data sheet should be prepared in conjunction with the general device questionnaire, and that is what we did.

DR. DAVID: So, are we are back to the top of the front page, classification recommendation?

MS. SCHULMAN: No, I moved to the supplemental sheet . Did you want to go back to the --

DR. HYLEK: No, we are all set. Go ahead.

MS. SCHULMAN: This is designed to provide the device description intended use, the risk of the device, the

recommended class again and the scientific support for the class and proposed level of controls. So, the generic type of device was the washer, washer-disinfectors . The advisory panel is the General Hospital and Personal Use Panel.

DR. DAVID: Should we put the slides up where we have the indication definitions to help the Panel?

MS . SCHULMAN: I guess we can go to No. 3. Is device an implant?

(There was a chorus of no.)

MS . SCHULMAN: No. That one was easy, and then the indications for use, we are going to put back up the indications for use that was put up earlier.

DR. EDMISTON: I think it was the definition was a device intended for medical use to clean, decontaminate and disinfect and dry reusable medical device. So, we can -- intended for medical purposes to clean, decontaminate or disinfect and dry reusable medical devices.

DR. HYLEK: Can you repeat that slowly? Oh, there it is. Is this it here? Okay.

MS . SCHULMAN : Is that agreeable?

DR. HYLEK: May I just ask, it is kind of a picky point but is decontaminate meant to be synonymous with disinfect by the word "or" there?

DR. PEARSON: No, it is clear, or decontaminate or disinfect and dry. So, clean and dry, decontaminate and

dry, disinfect and dry. I think those first three are ors, for the purpose of cleaning or decontaminating or disinfecting. There are three options. Decontaminate is not the same as disinfect. Decontaminate means you make it appropriate to be handled by medical staff. It can be handled safely without risk of transmitting disease as opposed to disinfect implies --

DR. HYLEK: Because it is really a matter of semantics but I think we have already said that sort of this general purpose, you know, has already been exempt and we are looking at the washer disinfection, you know, that process, that whole process. So, it almost seems like it should say, and argue with me, but it sounds like it should say, "Purpose is to clean, decontaminate and disinfect. " I mean that is sort of the or am I reading into that or are we like forcing all of these others that are already exempt to meet some new Class II? Is it an "or" or an "and"? It seems like it should be an "and."

DR. PEARSON: I think the semantic problem is general use versus general purpose. I think general purpose has a very specific definition, and those are those things that are non-patient care devices. What go under those general purpose things are like the beakers and the flasks and everything, and here where we are talking about general use these devices, washer-disinfectors or washers can be



used for a range of 'things excluding that general purpose category, i.e. , they can be used to clean a device. They can be used to decontaminate a device. They can be used to disinfect a device or some combination of those things, so, I think the problem is general use versus general purpose.

This general use has nothing to do with that general purpose, the non-patient care items.

MS . SCHULMAN : That is correct.

MR. PALOMARES: So what is the difference again between decontaminate and disinfect?

DR. PEARSON: There is a definition in the background but decontaminate means you make it so that it is safe to be handled by personnel whereas disinfect has something to do with patient transmission of disease.

MS . AVILA-MONGE : And it has a defined spectrum of what you are trying to get rid of. The other one is basically safety according to certain standards. In that case it would be OSHA standards so that someone can actually handle it and not be exposed to hazard.

DR. DAVID: Okay, let us move on.

MS . SCHULMAN: Okay, No. 5, the identification of risk to health presented by the device and there you can just --

MS . AVILA-MONGE : Pages 4 and 5?

DR. HYLEK: Was there a list on --

DR. DAVID: Yes, there is.

DR. HYLEK: If you agree with it, you can say, "Refer to Page," what did you say?

MS. AVILA-MONGE: Four and five.

DR. HYLEK: Does someone have that in front of them that they could just read the list? Would you, please read the list so we can all hear it, please?

MS. AVILA-MONGE: Page 4 starts with the potential risks and hazards, increased risks of nosocomial infection, that is cleaning failure can negatively impact terminal process. Failure of the device to achieve cycle parameters for terminal process. Failures are not detected. Incompatibility of the reusable medical device, and if you turn to Page 5 at the top it continues with exposure to chemical residues remaining on the reusable medical device, electrical hazards, firmware failures, software failures, release of toxic fumes and burns.

DR. HYLEK: So, we can simply refer to that on these sheets and not have to spell that out. Thank you.

And add any more if you felt it necessary.

Okay, any other questions? We are all set, I think. Go ahead.

MS. SCHULMAN: Okay, Question 6, the classification. That was Class II from the first sheet, and then the priority is a high, medium or low and that is how

quickly would you want us to write the regulation classifying these devices?

DR. HYLEK: What is that in terms of days, months? I don't know the terms.

MS . S CHULMAN : High, we would put it ahead of most everything else we have, but I don't know --

DR. HYLEK: That doesn't sound appropriate. Go ahead. It has to obviously coincide with the guidance document being turned back in, review of that and all of those.

DR. DAVID: I think that the risk to the public for lack of this document is not increasing.

DR. HYLEK: No. Low? Unless that means, and I don't know what that, I am not sure what that low means.

DR. DAVID: Since they are being controlled now.

DR. HYLEK: Right. So, low sounds reasonable. Okay.

MS . SCHULMAN: Question 7, if the device is an implant or life sustaining or life supporting and has been classified in a category other than III, but it hasn't and it is not; so, we can skip that.

Question 8, summary of information including clinical experience or judgment upon which classification recommendation is based and for example, you can say that it is based on the information presented at this panel meeting

or --

DR. HYLEK: That sounds really succinct and look at the videotape if you --

Okay, next?

MS. SCHULMAN: Question 9 is the identification of any needed restrictions on the use of the device and you can refer to Question 11A on the general device, and now, there is the prescription one and so we can skip that.

MS. SCHULMAN: Almost done. Question 10 we skip because that is only for Class I devices and that is where you would see it if you wanted to be exempt from premarket notification or included, and then Question 11, existing standards applicable to the device, device subassemblies, components or device materials, parts and accessories.

DR. DAVID: Those standards can be --

MS. SCHULMAN: Any standards that are known.

DR. EDMISTON: Those could be voluntary.

MS. AVILA-MONGE: The ones listed in the document before No. 7, is that what we are speaking of here?

MS. SCHULMAN: These are existing standards that we know. Are there any?

DR. DAVID: Existing standards that might be for electro-safety.

DR. HYLEK: Yes, device subassembly, I mean we don't really know what to put in there. What standards for

device subassembly?

DR. DAVID: Like electrical safety, like electromagnetic interferences.

DR. HYLEK: I see, okay.

DR. DAVID: We can put those down.

I just happen to know of a couple that might be applicable like electrical safety and electromagnetic interferences .

MS. RYDER: Would universal precautions apply here?

DR. HYLEK: That would be more handling you mean or --

MR. ULATOWSKI: Universal precautions is not a standard in the sense of this question.

DR. HYLEK: So, it sounds like we are through with the document?

MS . SCHULMAN: Yes .

DR. HYLEK: Okay. I will need to receive everyone's copy of the general device classification questionnaire as well as the supplemental data sheets.

Before we have the vote I want to again open the microphone if there are any additional comments, if anybody would like to approach the Panel before we vote, please don't hesitate to approach the microphone at this time.

Dr. Lin?

DR. LIN: Somebody just brought, Mr. John Friend

from Johnson & Johnson just pointed out to me that in this definition in the last part when you said, "Reusable medical devices, " I wanted to ask the Panel whether we should add critical, semicritical and non-critical devices rather than just saying, "Reusable medical devices." That may include the bedpan or --

DR. HYLEK: I think that hopefully we have already answered that question in the sense that we have been told that articles of just sort of general purpose like a bedpan, these non-critical items are already exempt, that we have made the assumption based on the information presented this afternoon that this pertains to medical devices. We are again making the assumption from what was presented that these would be critical and semicritical.

DR. DAVID: Can we hear the argument why there should be addition to this?

DR. HYLEK: Please approach and tell US who you are again and your affiliation and financial interests one more time?

MR. FRIEND: My name is John Friend I am Vice President of Regulatory Affairs for Advanced Sterilization Products, part of Johnson & Johnson.

The reason I raised this issue if 10 years from now you read in 21 CFR the Code of Federal Regulations just the term "reusable medical devices" and you go back to the

statutory definition of a medical device it doesn't recognize the specificity of your concern here.

By adding into this intended use statement critical, semicritical and non-critical devices you recognize what has already taken place within the agency and that is classification of bedpan washers ultrasonic cleansers, all of which have been exempt. If you, in my opinion, if you leave this definition as is, there is a risk of misinterpretation.

DR. HYLEK: In the guidance document it goes into some detail about what is considered a critical and I believe that was a body cavity, and I think the semicritical was a mucosal surface. Captain Barrett?

CAPT. BARRETT: That is right.

MR. FRIEND: It is from your own handout or from the handout that was given, if you compare that slide with what was given as a handout, there is a difference.

DR. HYLEK: Right, we have been -- certainly Dr. Pearson raised this issue of the problem with the term "general use washer. "

MR. FRIEND: No.

DR. HYLEK: And the -- I understand, yes.

MR. FRIEND : It is the last page of the handout under proposed definition of these devices.

DR. HYLEK: So, you would recommend to the Panel

that we would add something like in dry, reusable, critical and semicritical?

MR. FRIEND: I would recommend that you use the terminology and the statement that is within the handout.

DR. HYLEK: All right. Then we will have to have our FDA colleagues find the guidance document and the actual language that was used.

PARTICIPANT : Page 4 of the background.

DR. HYLEK: So, a washer and/or washer-disinfector is a device intended for medical purposes to clean, decontaminate or disinfect and dry reusable critical, semicritical and non-critical medical devices. So, we will just take it right from the document.

DR. PEARSON: May I ask whoever wrote the two versions of the definition if there is any real distinction between those two? I mean basically this includes any medical device. A medical device is either critical, non-critical or semicritical, and this says, "Reusable medical devices. " So, is there any, this is for my own education, is there any important distinction between those two definitions?

MR. ULATOWSKI: Captain Barrett is probably looking at me because I cut those words out.

(Laughter. )

MR. ULATOWSKI: For purposes of being succinct I



edited them out because I felt that you are saying, "Critical, semicritical and non-critical, " and that is everything anyhow. So, why say it in the first place? But I think Mr. Friend makes a point.

DR. HYLEK: Being consistent, I guess.

MR. ULATOWSKI: Being consistent but, also, looking forward, there may be some value. So, I wouldn't object .

DR. HYLEK: But isn't the non-critical already exempt ?

MR. ULATOWSKI: Non-critical , the bedpan washer is.

DR. HYLEK: But there is a whole host of non-critical.

MR. ULATOWSKI: There is a whole bunch of other things out there, yes.

DR. HYLEK: Come to the mike? Thank you.

MR. CAINE: Michael Caine, again, senior market manager with Geninger-Castle. I have no financial ties with the company other than being an employee. I would like to support Mr. Friend's recommendation because most of us do manufacture and produce washers with this wide range of processing capabilities, and we do, in fact, claim and advertise in those areas. So, I think it is very important to us. Also, in the area of cycle definitions and setting

up cycles they do vary, and if we don't have the capability within a given piece of equipment to do a non-critical processing cycle then it throws an unnecessary curve at us.

I, also, would like to point out that personally I don't like the use of decontamination in this definition only because to decontaminate is the entire process. It is all the way up to sterilization. It is the entire process of removing infectious microorganisms. So, whether you rinse it in water, wash it, disinfect it, pour chemicals on it or sterilize, you are still going through that process. So, it is undefined to those of us who are trying to educate our customer base, and one other thing. If I submit for a washer decontaminator, what classification am I in?

DR. HYLEK: Good point. Comments from the Panel?

DR. PEARSON: I have a question.

DR. HYLEK: Yes, Dr. Pearson.

DR. PEARSON: An example of a non-critical device that you would reprocess in a washer disinfectant other than those waste receptacle things?

MR. CAINE: A suction bottle.

DR. PEARSON: Suction bottle?

DR. HYLEK: I am not sure that is an accessory or not .

DR. PEARSON: I am just loath to come up with one that would fall into this.

DR. HYLEK: There must be.

DR. PEARSON: I was just curious as to an example.

DR. HYLEK: So, it sounds like the Panel, we all agree that we are going to use the definition that is in the document as I just read for everyone and the second is if there are comments and reactions to taking out the word "decontaminate"?

MS. RYDER: There are definitions in the guidance document for each one of these terms, and they are separate and distinct.

DR. HYLEK: So, what is the distinction between decontaminate and disinfect because I don't have it open, and it looks like you do?

MS. RYDER: Do you want me to read each definition?

DR. HYLEK: Is it long or can you quickly read decontaminate?

MS. RYDER: Decontaminate according to OSHA, quote, the use of physical or chemical means to remove, inactivate or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use or disposal. In common usage decontamination generally refers to all pathogens, microorganisms capable of producing disease or infection not

just those transmitted by human blood, and they have in parentheses that that is an AMI definition, 1995.

DR. HYLEK: And what about disinfect?

MS. RYDER: A chemical agent that eliminates a defined scope of pathogenic organisms but not necessarily all microbial forms, that is bacterial endospores.

DR. HYLEK: So, decontaminate it sounds like is really synonymous with sterilization?

(There was a chorus of no.)

DR. HYLEK: Yikes.

MR. ULATOWSKI: It is simply a level necessary for handling the products during the process of reprocessing.

DR. HYLEK: So, what are your thoughts about it? Shall we leave it all in?

MR. ULATOWSKI: I think there are going to be claims made for products, and we are just trying to cover the bases here within the spectrum of possibilities.

DR. PEARSON: And those are very well recognized distinctions in terms of cleaning and disinfection and sterilization.

DR. HYLEK: But the provocative question raised is what will you do if some savvy industry or whatever comes up with we want to market a washer-decontaminator; is that possible or you know?

MR. ULATOWSKI: If someone should we will say,

"Hey, it is classified Class II," if that is what the final vote is.

DR. HYLEK: Okay, are there any more comments?

If not, it is probably time to move to a vote and our consumer industrial reps cannot vote, and basically I am going to read. A washer, washer-disinfector is a device intended for medical purposes to clean, decontaminate or disinfect and dry reusable critical, semicritical and non-critical medical devices, that the Panel has deemed that these should be Class II. We feel that they are under other which we checked off on this list would be voluntary standards, some succinct and not too burdensome user information to try to improve behavior and help the individuals down in central supply and adoption of recommendations contained within the released guidance document that is soon to be back from the public and industry.

so, I guess at this point for those individuals who will be voting if you could just state yes or no as your vote we can just go around this way.

Dr. Pearson?

DR. PEARSON: Yes .

DR. HYLEK: Dr. Edmiston?

DR. EDMISTON: Yes .

DR. HYLEK: Yes, you are a voting member.

MS. AVILA-MONGE: Yes, I am sorry. My vote is  
yes .

DR. HYLEK: I could only assume that was the  
question.

MS . RYDER : Yes .

DR. DAVID: Yes.

DR. HYLEK: And I will vote yes.

so, that is that part of it, and what do we have  
left?

Thank you, everyone for your attention and  
sticking with us through what seemed to be a fairly arduous  
task at certain points but this is not the usual fund of  
knowledge for an internist. So, thanks everybody, have safe  
trips home and the meeting is adjourned.

(Thereupon, at 3:12 p.m., the meeting was  
adjourned. )